K080506

510(k) Summary

JUN -9 2008

A. GENERAL INFORMATION

1. Submitter's Name:	Martin Manufacturing Co., LLC
2. Address:	621-101 Hutton St. Raleigh, NC 27606
3. Contact Person:	Michael Zapata III
4. Date prepared:	25 February 2008
5. Registration Number:	Not currently registered
6. Telephone Number:	(919) 741-4401
7. Fax Number:	(919) 829-8045

B. DEVICE

1. Proprietary or Trade Name:	Martin Chair C4S1
2. Common Name:	Mechanical Wheelchair
3. Classification Name:	Wheelchair, Mechanical
4. Classification Panel(s):	General Hospital, Physical medicine
5. Product Code(s):	IOR, LGX, FRZ
6. Class for New Device:	Class I
7. Regulation Number:	890.3850

C. INDICATIONS FOR USE

Martin Chair Model C4S1 is intended for use for providing mobility to persons limited to a sitting position. It is specifically indicated to transfer a patient to and from a wheelchair.

D. DESCRIPTION OF THE DEVICE

The Martin Chair Model C4S1 mechanical wheelchair is an indoor/outdoor wheelchair that has a base with two larger rear wheels and two smaller front wheels and a seat. The wheelchair is intended to be manually propelled by a person seated in the wheelchair or by an attendant or clinician. The device is made from composites of steel, plastics and fabrics. The wheelchair is for use by adult persons.

The wheelchair can be secured to a compatible, electrically elevated examination table which allows for the seat of the wheelchair to become part of the examination table. This removes the need for the patient to be lifted during transfer from the wheelchair to the examination table. The wheelchair is latched to the examination table and the side frame and wheels are removed for the examination. The sides and wheels are replaced prior to lowering the examination table allowing the wheelchair to be used according to its intended use.

The Martin Examination Table is a 510(k) exempt device, 21 CFR 878.4960, product code LGX. It is an accessory to the Martin Chair. It is a device intended as a powered examination table to provide positioning and support to patients during general examinations and procedures. It is intended for medical purposes as an electrically operated table with movable components that can be adjusted to various positions, the same intended use as other currently marketed powered tables. The Martin Examination Table is a standard powered examination table that includes standard components and features of other currently marketed powered examination tables including side rails for additional safety. The Martin Examination Table includes latches under the seat cushion that are compatible with the fixed metal receivers of the Martin Chair Model C4S1,

E. PERFORMANCE TESTING

The Martin Chair Model C4S1 mechanical wheelchair meets the applicable FDA recognized ANSI/RESNA consensus standards tested by Human Engineering Research Laboratories (HERL) for mechanical wheelchairs and has successfully passed testing. Data within the 510(k) demonstrates successful performance against flame retardant standards.

The Martin Examination Table has been tested to in accordance with standards: UL 60601-1, UL 60601-1-2, and CSA 22.2 No 601-1.

F. LEGALLY MARKETED DEVICE FOR SUBSTANTIAL EQUIVALENCE COMPARISON

	Mechanical Wheelchair Predicate	Table Predicate	Patient Transfer Predicate
Manufacturer:	Invacare Corporation	Midmark Corporation	Nova Technologies, Inc.
Model:	Terminator	411	Novabed Patient Transfer System
Cleared Under:	K012167	K894134	K874448, K964246
Date Cleared:	August 1, 2001	08/28/1989	December 17, 1987 January 22, 1997
Class:	I	I	II
Regulation Number:	890.3850	878.4960	890.3860 880.5100
Product Code(s):	IOR, FRZ, LGX	LGX	FRZ, FNL, IOR

G. SUMMARY OF SUBSTANTIAL EQUIVALENCE COMPARISON

The new device and the predicate devices have the same intended use which is to provide mobility to persons limited to a sitting position and to transfer patients to and from a wheelchair.

The wheelchair is manually powered and has similar weight bearing capacity. The overall dimensions and materials are similar. The ability to remove the side rails and/or wheels via a contained, quick release axle is also similar compared to Invacare Terminator, K012167. The Invacare Terminator uses an enclosed camber to hold the rear quick release axle. Similarly, the Martin Chair has an enclosed quick release axle and an enclosed positioning pin that secure the side frame of the wheelchair. Like the predicates, the Martin Chair has been tested to and found to meet the applicable FDA recognized ANSI/RESNA consensus standards tested by HERL for mechanical wheelchairs.

The one technological difference between the new device and the predicates is the ability to latch to the Martin Examination Table thus facilitating patient transfer. As described within the 510(k), processes for transferring patients in and out of wheelchairs have previously been established by both the predicate wheelchairs and the Novabed Patient Transfer System. While patient transfer currently takes place routinely using the predicated wheelchair, the technological features between the Martin Chair and the Novabed Patient Transfer System are similar in that both devices provide a means for securing the patient during

transfer and placing the patient directly onto the examination table. The method of patient transfer is well established and does not present new issues of safety and effectiveness.

Thus the Martin Chair is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

Martin Manufacturing Co., LLC
% Mr. Michael Zapata, III
President
621-101 Hutton Street
Raleigh, North Carolina 27606

Re: K080506
Trade/Device Name: Martin Chair Wheelchair Model C4S1, Martin Examination Table
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR, LGX
Dated: May 23, 2008
Received: May 23, 2008

Dear Mr. Zapata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080506

Device Name: **Martin Chair Wheelchair Model C4S1**

Martin Examination Table

Indications For Use:

The Martin Chair Model C4S1 is indicated for providing mobility to persons limited to a sitting position. It is also specifically indicated to transfer a patient to and from the Martin Examination Table.

The Martin Examination Table is indicated for use during diagnostic examinations or surgical procedures to support and position a patient.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080506